

## Food and Drug Administration, HHS

## Pt. 26, Subpt. A, App. C

EC documents may be viewed on the European Commission Pharmaceuticals Units web site at <http://dg3.eudra.org>.]

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation, or administrative action relating to proprietary medicinal products as extended, widened, and amended. Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products as extended, widened and amended.

Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, as widened and amended.

Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.

Council Regulation EEC No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use.

Guide to Good Distribution Practice (94/C 63/03).

Current version of the Guide to Good Manufacturing Practice, Rules Governing Medicinal Products in the European Community, Volume IV.

### 2. For the United States:

[Copies of FDA documents may be obtained from the Government Printing Office, 1510 H St. NW., Washington, DC 20005. FDA documents, except the FDA Compliance Program Guidance Manual, may be viewed on FDA's Internet web site at <http://www.fda.gov>.]

Relevant sections of the United States Federal Food, Drug, and Cosmetic Act and the United States Public Health Service Act.

Relevant sections of Title 21, United States Code of Federal Regulations (CFR) Parts 1–99, Parts 200–299, Parts 500–599, and Parts 600–799.

Relevant sections of the FDA Investigations Operations Manual, the FDA Regulatory Procedures Manual, the FDA Compliance Policy Guidance Manual, the FDA Compliance Program Guidance Manual, and other FDA guidances.

## APPENDIX B TO SUBPART A OF PART 26— LIST OF AUTHORITIES

1. For the United States: In the United States, the regulatory authority is the Food and Drug Administration.

2. For the European Community: In the European Community, the regulatory authorities are the following:

Belgium: Inspection générale de la Pharmacie, Algemene Farmaceutische Inspectie.

Denmark: Laegemiddelstyrelsen.

Germany: Bundesministerium für Gesundheit for immunologicals: Paul-Ehrlich-Institut, Federal Agency for Sera and Vaccines.

Greece: Εθνικός Οργανισμός Φαρμάκου, Ministry of Health and Welfare, National Drug Organization (E.O.F).

Spain: For medicinal products for human use: Ministerio de Sanidad y Consumo, Subdirección General de Control Farmacéutico. For medicinal products for veterinary use: Ministerio de Agricultura, Pesca y Alimentación (MAPA), Dirección General de la Producción Agraria.

France: For medicinal products for human use: Agence du Médicament. For veterinary medicinal products: Agence Nationale du Médicament Vétérinaire.

Ireland: Irish Medicines Board.

Italy: For medicinal products for human use: Ministero della Sanità, Dipartimento Farmaci e Farmacovigilanza. For medicinal products for veterinary use: Ministero della Sanità, Dipartimento alimenti e nutrizione e sanità pubblica veterinaria-Div. IX.

Luxembourg: Division de la Pharmacie et des Médicaments.

Netherlands: Staat der Nederlanden.

Austria: Bundesministerium für Arbeit, Gesundheit und Soziales.

Portugal: Instituto da Farmácia e do Medicamento (INFARMED).

Finland: Lääkelaitos/Läkemedelsverket (National Agency for Medicines).

Sweden: Läkemedelsverket-Medical Products Agency.

United Kingdom: For human use and veterinary (non-immunologicals): Medicines Control Agency. For veterinary immunologicals: Veterinary Medicines Directorate.

European Community: Commission of the European Communities. European Agency for the Evaluation of Medicinal Products (EMA).

## APPENDIX C TO SUBPART A OF PART 26— INDICATIVE LIST OF PRODUCTS COVERED BY SUBPART A

Recognizing that precise definition of medicinal products and drugs are to be found in